Remarks

Claims 43-46, 49-53, and 55-57 remain pending. Claims 58 – 66 are new. Claims 43, 44, 51, and 55 are amended.

On the Office Action Summary that accompanies the Office Action mailed December 20, 2007, the Disposition of Claims appears to recite the pending claims in error. Claim 42 stands cancelled. The body of the Office Action correctly recites the pending claims as beginning with Claim 43.

The Office Action contains a rejection of Claims 43-46, 49-53, and 55 under 35 USC §103(a) as obvious over *Norling et al.* (US 5,958,458) in view of *Busetti et al.* (US 5,788,987). Applicants request reconsideration.

In this case, the cited references fail to establish a *prima facie* case of obviousness. As stated in MPEP §2141.02, in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. The present invention provides an effective pharmaceutical formulation that includes a single-ingredient substrate. The cited references, however, describe a multi-ingredient substrate. The references do not teach or suggest a single-ingredient substrate. In fact, since the references propose multi-ingredient substrates, the references teach away from the single ingredient formulation of the present invention. Further, since the multi-ingredient substrates of the cited references achieve the stated purpose of the reference, there is no motivation to alter the formulations of the references. As such, the references fail to support a *prima facie* case of obviousness.

As amended, Claim 43 defines the present invention to include a particulate pharmaceutical substrate which is exclusively dibasic calcium phosphate. To the contrary, *Norling et al.* describes a substrate that includes multiple ingredients. For example, at Col. 2, lines 8 – 32 of *Norling et al.,* the substrate, or "core" as that term is used in the reference, is described as having a w/w % composition of calcium phosphate along with additional components in order to impart a specified friability and flow angle. The *Norling et al.* reference notes a desire to provide a "sufficient robustness" to a core by **formulating** the substrate material into a particulate core. *Norling et al.* do not teach the use of a single substrate material, in the absence of any additional ingredient, as useful in pharmaceutical formulations. In fact, quite to the contrary, *Norling et al.* teach

away from the present invention by providing that the material must be subjected to further formulation in order to be useful as a particulate substrate material.

Moreover, since the cores taught by *Norling et al.* achieve their stated purpose, namely to provide a core with specified particle form, flowability, crushing strength, and friability as identified at Col. 18, line 38 – Col. 19, line 54, those skilled in the art would not modify the cores taught by *Norling et al.* Rather, as noted, *Norling et al.* teach away from any such modification because the formulation of the core is described as necessary to impart the desired physical attributes.

Thus, the *Norling et al.* reference fails as a primary reference to support a prima facie case of obviousness. As such, Applicants respectfully request that the Examiner withdraw the rejection and allow all of the pending claims.

Should the Examiner have any remaining issues, he is encouraged to telephone the undersigned for expeditious handling.

Respectfully submitted,

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